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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/599,274	06/22/2000	Karl Andrew Garrill	PG4114	7879

23347 7590 03/16/2005

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EXAMINER	
FOSTER, JIMMY G	
ART UNIT	**PAPER NUMBER**
3728	

DATE MAILED: 03/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/599,274	GARRILL ET AL.
	Examiner	Art Unit
	Jimmy G Foster	3728

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 12-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 12-16* is/are rejected.

7)☒ Claim(s) *10* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/18/03,8/23/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1) Claims 1-10 and 12-16 patentably distinguish over the prior art.

2) The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3) Claims 1-9 and 12-16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 2-5, 9, 13, 14 and 17 of U.S. Patent No. 6,315,112 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent claim 1 covers all of the subject matter set forth in the present claim 1, including a drug formulation including a drug or drugs and an HFA propellant, the drug formulation in a pressurized container, a moisture absorbing material, and a sealed pouch/package, except that the pouch is not recited as being adapted to sealably receive the pressurized container. However, claim 13 suggests providing the pressurized container in the package/pouch, since it recites using a one-way valve to permit propellant from the pressurized container to leak from the package.

Accordingly it would have been obvious to have sealably received the pressurized container in the pouch/package.

Regarding claim 2, it would have further been obvious in view of patent claim 2 of the same embodiment to have provided the pressurized container as a metered dose inhaler. Regarding claims 3, it would have further have been obvious in view of patent claim 3 of the same embodiment to have used an albuterol sulfate as the drug. Regarding claim 4, it would have further been obvious in view of patent claim 4 of the same embodiment to have used HFA 134a as the propellant. Regarding claim 5, it would have been obvious in view of claim 5 of the same embodiment to have used a desiccant as the moisture absorbent. Regarding claim 6, it would have further been obvious in view of patent claim 17 of the same embodiment to have employed silica gel as the desiccant material.

Regarding claims 8 and 9, it is well known to loosely or securely provide a desiccant with a medical content in an outer package. This would inherently permit selective inclusion of the desiccant in the package or ensure that the desiccant does not contaminate the medic content. Accordingly, it would have further been obvious been obvious to have provided the desiccant loosely in the package or secured in the package.

Regarding claims 12-16 all the drugs recited therein are asserted by the examiner to be known for use in asthma inhalers. These drugs include fluticasone propionate, a solvate thereof, beclomethasone dipropionate, a solvate thereof, a salt, ester or solvate of salmeterol, and a solvate of ipratropium. It would therefore have been further obvious to have provided

any specific one of these drugs as the drug of patent claim 14 for treating asthma.

4) Claims 1-9 and 12-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 2-4, 8 and 10 of U.S. Patent No. 6,390,291 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent claim 10 covers all of the subject matter set forth in the present claims 1 and 5, including a drug formulation including a drug or drugs and an HFA propellant, the drug formulation being in a pressurized container, a moisture absorbing material/desiccant, and a sealed pouch/package within which are the desiccant and the pressurized container.

Regarding claim 2, it would have further been obvious in view of claim 2 of the same embodiment to have made the container as a metered dose inhaler. Regarding claim 3, it would have further been obvious in view of claim 3 of the same embodiment to have used an albuterol sulfate as the drug. Regarding claim 4, it would have further been obvious in view of patent claim 4 of the same embodiment to have used a HFA 134a as the propellant. Regarding claims 6, it would have further been obvious in view of patent claim 8 of the same embodiment to have provided a silica gel as the desiccant.

Regarding claims 12-16 all the drugs recited therein are asserted by the examiner to be known for use in asthma inhalers. These drugs include fluticasone propionate, a solvate thereof, beclomethasone dipropionate, a

solvate thereof, a salt, ester or solvate of salmeterol, and a solvate of ipratropium. It would therefore have been further obvious to have provided any specific one of these drugs as the drug of patent claim 10 for treating asthma.

5) Claim 10 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jimmy G Foster whose telephone number is (571) 272-4554. The examiner can normally be reached on Mon-Fri, 8:45 am - 5:15 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on (571) 272-4562. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

Jimmy G Foster
Primary Examiner
Art Unit 3728

JGF
15 March 2005